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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,588	01/16/2001	Melton B. Affrime	AL01132K	4299

7590 06/16/2005

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EXAMINER

DELACROIX MUIRHEI, CYBILLE

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 06/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/760,588	Applicant(s) AFFRIME ET AL.	
	Examiner Cybille Delacroix-Muirheid	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 69-84 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 69-84 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

The following is responsive to applicant's amendment received March 28, 2005.

Claims 1-68 are cancelled. New claims 69-84 are added. Claims 69-84 are currently pending.

The previous obviousness-type double patenting rejection set forth in paragraph 2 of the office action mailed Sep. 27, 2004 is withdrawn in view of applicant's amendment and the remarks contained therein.

The previous claim rejection under 35 USC 103(a), set forth in paragraph 1 of the office action mailed Sep. 27, 2004 is withdrawn in view of applicant's amendment and the remarks contained therein.

However, applicant's amendment has necessitated the following new ground(s) of rejection.

New Ground(s) of Rejection

Claim Rejection(s)—35 USC 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 69-84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The limitation "about" in these claims is a relative term, which renders the claims indefinite. The expression "about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree of closeness or proximity, and

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thus one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

“The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. A secondary purpose is to provide a clear measure of what applicants regard as the invention so that it can be determined whether the claimed invention meets all of the criteria for patentability and whether the specification meets the criteria of 35 USC 112, first paragraph with respect to the claimed invention.” Please see MPEP 2173.

Because the limitation “about” would invite subjective interpretations, the Examiner respectfully submits that the public would not be informed of the boundaries of what constitutes infringement of the present claims and thus the claims do not meet the requirements of 35 USC 112, second paragraph.

PLEASE NOTE: in the absence of a definition, the term “about”, as it relates to the number of days of administration, will be interpreted as being at least + or – 5 days.

Claim Rejection(s)—35 USC 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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2. Claims 69-84 are rejected under 35 U.S.C. 102(e) as being anticipated by Kou 6,100,274 (reference already of record).

Kou disclose the invention substantially as claimed. Specifically, Kou discloses a method of treating allergic reactions in a mammal, the method comprising orally administering to the mammal an anti-allergic effective amount of a pharmaceutical composition containing (preferred, 5-10 mg/day in single or divided doses) descarbonylethoxyloratadine, i.e. desloratadine. The most preferred amount is 5 mg, once a day. Kou discloses that desloratadine possesses antihistaminic properties. Please see the abstract; col. 5, lines 43-56; claim 1.

The claims are anticipated by Kou because Kou discloses administration of a pharmaceutical composition containing an identical compound, i.e. desloratadine, at identical dosages, i.e. 5 mg/day, using applicant's claimed method steps. Accordingly, treatment of nasal and non-nasal symptoms of seasonal and perennial allergic rhinitis as well as chronic idiopathic urticaria in a human of 12 years or older would be inherent. Moreover, in the absence of a definition of the term "about" as it pertains to the number of days of administration, the examiner respectfully submits one of ordinary skill in the art is able to readily envisage about 10 days of treatment from the disclosure of Kou and is therefore anticipated.

Concerning the claimed pharmacokinetic profile/blood and plasma concentrations, these are inherent within the dosages achieved and administered to mammals suffering from allergies.

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Additionally, it is reasonable to conclude that the same patient is being administered the same composition by the same mode of administration in the same amount in both the instant claims and the Kou reference. The fact that applicant may have discovered yet another beneficial effect from the method set forth in the prior art does not mean that they are entitled to received a patent on the method. "It is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable." In re Woodruff, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990).

Furthermore, it does not appear that the claim language or limitation result in a manipulative difference in the method steps when compared to the prior art disclosure. Please see Bristol-Meyers Squibb Co. v. Ben Venue Laboratories, 58 USPQ2d 1508 (CAFC 2001).

Conclusion

Claims 69-84 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybille Delacroix-Muirheid** whose telephone number is **571-272-0572**. The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Christopher Low**, can be reached on **571-272-0951**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDM

June 13, 2005


REBECCA COOK
PRIMARY EXAMINER
GROUP 1200/1614